UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE PHILIP MORRIS INTERNATIONAL INC. SECURITIES LITIGATION

Master File No. 1:18-cv-08049 (RA)

No. 1:18-cv-08814 (RA)
1:18-cv-09856 (RA)

OPINION & ORDER
CLASS ACTION

RONNIE ABRAMS, United States District Judge:

Lead plaintiffs Union Asset Management Holding AG and Teamsters Local 710 Pension Fund (collectively, "Plaintiffs") bring this putative class action against Philip Morris International ("PMI" or the "Company") and several current and former officers of the Company[1] (collectively, "Defendants"), alleging that Defendants withheld material information about known health risks associated with "iQOS," a cigarette-alternative device for which they sought approval from the United States Food and Drug Administration ("FDA"). According to Plaintiffs, the failure to timely disclose that information constitutes securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Securities and Exchange Commission ("SEC") Rule 10(b)-5.

On February 4, 2020, the Court dismissed Plaintiffs' Consolidated Amended Class Action Complaint on the basis that they had failed to adequately plead the required elements of falsity and

[1] Plaintiffs bring claims against André Calantzopoulos, Martin G. King, Patrick Picavet, Jacek Olczak, Manuel C. Peitsch, and Frank Lüdicke (collectively, the "Individual Defendants").

scienter. The Court granted Plaintiffs leave to amend their complaint with respect to one subset of their claims—those concerning four studies of the chemical composition of the aerosol generated by iQOS, which Plaintiffs allege were belatedly disclosed to the FDA and contradicted the Company's positive statements about the potential health benefits of the device, as compared to cigarettes. Plaintiffs timely amended their complaint with additional allegations about these studies. Now before the Court is Defendants' motion to dismiss that amended complaint.

Because the amended complaint fails to adequately cure the deficiencies identified in the Court's prior opinion, and the FDA's July 2020 approval of iQOS as a "modified risk tobacco product" severely undermines any allegations of falsity, that motion is granted in full.

BACKGROUND

The Court assumes familiarity with the factual background of this case, which was recounted in its previous opinion, Dkt. 123 ("Feb. 2020 Opinion"). The following is a brief overview of those facts and procedural history that are relevant to the instant motion.

I. Factual Background

The facts alleged in the Second Consolidated Amended Class Action Complaint ("Complaint"), Dkt. 134, are assumed to be true for the purposes of this motion. *See, e.g., Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 35 (2d Cir. 2017). The Court also considers facts drawn from "legally required public disclosure documents filed with the SEC" and from various other documents, incorporated into the Complaint by reference, that contain the statements that Plaintiffs allege were false or misleading. *See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.,* 493 F.3d 87, 98 (2d Cir. 2007). The Court also takes judicial notice of the FDA's approvals of iQOS, and the scientific reviews associated with those approvals. *See In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 96 n.4 (2d Cir. 2017).

A. iQOS and the FDA Approval Process

To combat the years-long decline in worldwide cigarette sales, PMI has begun to develop and commercialize smoke-free alternatives to cigarettes, first in Japan and then in the United States. Compl. ¶¶ 3-5. iQOS, a device into which a specially designed tobacco unit is inserted and heated to generate an aerosol, is the Company's "flagship" smoke-free product. *Id.* ¶¶ 3, 34. In order "to sell iQOS in the United States, and for permission to market it as a Modified-Risk Tobacco Product ('MRTP')," PMI had to obtain FDA approval. *Id.* ¶ 42. PMI thus sought two distinct authorizations from the FDA: to sell the iQOS, and to market it as a MRTP. *See id.* ¶ 134. "The MRTP designation would permit [PMI] to market iQOS in the U.S. as presenting less harm or risk of disease to users than traditional tobacco." *Id.* ¶ 42. In December 2016, the Company submitted a Modified Risk Tobacco Product Application ("MRTPA") to the FDA for iQOS, which was formally accepted "for substantive scientific review" in May 2017. *Id.* ¶¶ 4-5, 45.

Pursuant to Section 911(g) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), a tobacco product is eligible for a "risk modification order" if it meets two conditions:

> that the product "as it is actually used by consumers, will (a) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (b) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."

Id. ¶¶ 46-47 (quoting 21 U.S.C. § 387k(g)(1)). Tobacco products that do not meet the above requirements may be marketed under a different type of order if, among other things, "the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies." 21 U.S.C. § 387k(g)(2)(A)(iv). This type of order, which requires that "the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the

market, *id.* § 387(k)(g)(2)(B)(ii), is commonly known as a "exposure modification order," *see* Compl. ¶ 46.

B. The Four Undisclosed Studies

In its application to the FDA, the Company asserted that "the weight of the evidence that [its technology] significantly reduces harm and the risk of tobacco-related disease to individual tobacco users is compelling." *Id.* ¶ 49. The Company outlined the steps it took to make that assessment, namely the completion of eight "clinical studies with adult smokers" in the "U.S., Europe, and Japan between 2013 and 2015." *Id.* ¶¶ 50-53, 63. According to Plaintiffs, this "clinical" research on iQOS—which by definition involved investigation into human subjects, *see id.* ¶ 57—analyzed "only a subset of the 93 compounds" that the FDA had classified as "harmful and potentially harmful constituents," commonly referred to as "HPHCs." *Id.* ¶ 87. In other words, these "close-ended" studies did not purport to analyze every compound on the FDA's list of HPHCs nor "whether iQOS contained harmful substances that were not present in combustible cigarettes at all." *Id.* ¶¶ 89, 91.

Meanwhile, PMI had conducted "at least four additional scientific studies," none of which were included in the Company's initial application to the FDA (the "Four Undisclosed Studies"). *Id.* ¶ 85. Unlike the clinical research, these studies "used an 'open-ended' approach that compared *all* the chemicals present in iQOS with all the chemicals present in a combustible cigarette." *Id.* ¶ 91 (emphasis in original). The studies, characterized as "nontargeted differential screenings" ("NTDS"), compared the chemical composition of the smoke produced by iQOS with the smoke produced by a conventional cigarette, without any testing on humans or animals. *Id.* ¶ 106. In the Company's words,

> In contrast to the fully quantitative targeted analysis for a list of 54 harmful or potentially harmful constituents (HPHCs) routinely used by PMI to evaluate product emissions, NTDS

> … provides a comprehensive chemical characterization and semi-quantification of complex mixtures with no predefined target compounds and was used to identify differences beyond those selected 54 HPHCs.

Id. ¶ 91.

"Each of these studies was commenced before [the Company]'s FDA MRTPA was ever made, and two of the studies had already concluded half a year before that submission." *Id.* ¶ 85 (emphases omitted). Study 1 and Study 2 each began on March 1, 2016 and ended on June 6, 2016. *Id.* ¶ 92. Study 3 and Study 4 each began on October 1, 2016 and ended on January 1, 2017. *Id.* ¶ 94. Yet the Company did not submit these studies to the FDA, or disclose them to the public, until a December 8, 2017 amendment to its MRTPA, six weeks before a meeting of the FDA's Tobacco Products Scientific Advisory Committee ("TPSAC"), a panel of industry experts who make recommendations to the FDA about whether a particular product should be approved. *Id.* ¶¶ 9, 85, 146. The December 8 amendment was one of fourteen made by the Company in the "first year alone." *Id.* ¶ 108.

Each of the Four Undisclosed Studies "showed … increases in dozens of dangerous chemicals in [iQOS] as compared to conventional cigarettes," findings that Plaintiffs characterize as "stunning." *Id.* ¶ 96. Along with the studies themselves, PMI submitted to the FDA a Toxicological Assessment Report that summarized their results, which disclosed that 80 compounds were of "higher concentration or new" in iQOS when compared to a conventional cigarette. *Id.* ¶ 98. Of these 80 chemicals, [PMI] acknowledged that "4 compounds are classified mutagens/carcinogens" and "8 compounds present potential genotoxic concerns." *Id.* ¶ 98. PMI subsequently disclosed that it "did not evaluate the effect that inhaling these chemicals had on human subjects." *Id.* "The four chemicals identified in the Four Undisclosed Studies that [the Company] admitted were classified as mutagens/carcinogens were glycidol; 1,2-Propanediol; 3-

chloro-, 2- Furanmethanol; and furfural." *Id.* ¶ 101. According to Plaintiffs, "Glycidol has been identified as 'probably carcinogenic to humans (Group 2A)' by the International Agency by the National Institute for Occupational Safety and Health … for Research on Cancer since the year 2000," and "furfural has been identified by the National Institute for Occupational Safety and Health … as having adverse respiratory effects since the 1980s." *Id.* ¶ 102.

Plaintiffs further allege that PMI's failure to immediately disclose these studies was inconsistent with the FDA's recommendation that product applicants "complete [product-sample] analyses within a short timeframe," given that "the Four Undisclosed Studies did not require a significant amount of time to complete and submit." *Id.* ¶¶ 104-105. According to a former PMI employee who "was involved in the Company's iQOS trials," "the results of the Four Undisclosed Studies were evident when the studies ended." *Id.* ¶ 106. Plaintiffs also proffer the opinion of an expert that supports the conclusion "that the results of the Four Undisclosed Studies were evident when the studies ended, or at most a few weeks thereafter, and that the reports describing the studies could have been issued in a matter of weeks after the studies' completion." *Id.* ¶ 107.

C. The TPSAC Meeting

On December 22, 2017—two weeks after the disclosure of the four non-clinical studies--, the FDA published a "Briefing Document" in preparation for the TPSAC meeting. *Id.* ¶ 112. That document contained assessments, conclusions, and/or recommendations written by individual FDA reviewers for TPSAC panel members. *Id.* The three paragraphs summarized the studies' results and indicated "that iQOS contained significantly larger amounts of potentially harmful chemicals, including carcinogens, than combustible cigarettes." *Id.* ¶ 113. This document also stated that the levels of "acetol, glycidol and 2-propen-1-ol" were not included in PMI's original applications and that the studies indicated "compounds of toxicological concern present in higher

quantities in [iQOS] aerosols than in reference cigarette smoke." *Id.* ¶¶ 116, 120. According to that document, the FDA "could not determine the risks of harm and tobacco-related diseases presented by iQOS based on [PMI's] submission because '[a] full characterization of the chemical composition of the aerosol produced by the IQOS is unknown.'" *Id.* ¶ 120.

PMI's submission was presented and discussed at a TPSAC meeting that took place on January 24 and 25, 2018. *Id.* ¶ 121. At that meeting, a committee member asked Defendant Manuel Peitsch, PMI's Chief Scientific Officer for Reduced-Risk Products, *see id.* ¶ 27, "whether the Company had tried to measure exposure in humans to the chemicals found in higher concentrations in iQOS as part of the Four Undisclosed Studies," *id.* ¶ 121. Peitsch responded in the negative, indicating that "the Company had conducted its clinical studies using a subset of HPHCs before the Company had determined whether there were other potentially harmful chemicals in iQOS." *Id.* (emphasis omitted). Multiple committee members remarked that they had insufficient time with the data to determine the health implications of the additional compounds identified in the studies. *See id.* ¶¶ 124-127. At the end of the TPSAC meeting, the committee recommended rejection of "both of the risk reduction claims" for which the Company had sought approval—namely, that the Company's "scientific studies have shown that switching completely from cigarettes to the iQOS system can reduce the risks of tobacco-related diseases" and "that switching completely to iQOS presents less risk of harm than continuing to smoke cigarettes." *Id.* ¶¶ 129, 154.

On January 25, 2018, following this vote of the TPSAC committee, The New York Times published an article entitled "F.D.A. Panel Rejects Philip Morris's Claim That Tobacco Stick Is Safer Than Cigarettes." *Id.* ¶ 155. "On this news, the Company's stock price fell from $110.06 per share to $107.49 per share on January 25, 2018—a decline of $2.57 per share." *Id.* ¶ 156.

D. FDA Approvals

On April 30, 2019—more than eighteen months after the stock drop and seven months after the initial complaint was filed in this action—the FDA announced that it had authorized the marketing and sale of iQOS. *Id.* ¶ 134. The agency emphasized, however, that its announcement was "not a decision on the separate modified risk tobacco product (MRTP) applications that the company also submitted for these products to market them with claims of reduced exposure or reduced risk." *Id.* ¶ 134. In conjunction with the announcement, the FDA issued a "scientific review" explaining its decision, which, among other things, discussed the Company's "assessment" of four carcinogens identified in the undisclosed studies. *Id.* ¶ 136; *see also* Dkt. 138, Declaration of Kevin M. McDonough ("McDonough Decl."), Ex. 12 ("April 2019 Scientific Review").

In the section on "toxicological assessment," the April 2019 Scientific Review reported that the Four Undisclosed Studies "found 80 chemicals that were either present in higher concentration in [iQOS] aerosols than [cigarette] smoke or not found in [cigarette smoke]: 4 are possibly carcinogenic, 30 are identified by the applicant as Generally Recognized as Safe (GRAS), and 46 additional ingredients (mostly flavoring ingredients)." April 2019 Scientific Review at 32. With respect to the Company's conclusion that "the four possible carcinogens… do not pose a toxicological concern because the levels are below recognized dietary or occupational exposure limits," the FDA found that the methodology used to assess the toxicology of those carcinogens was "not considered adequate." *Id.* The FDA concluded that the Company's data did "not support a conclusion that these pose no risk to IQOS users," but that "the levels of exposure to these possible carcinogens appear low and when considered with other data does not preclude a conclusion the products are appropriate for protection of public health." *Id.*

The April 2019 Scientific Review also discussed studies that indicated that "measured HPHC levels (except nicotine) were reduced in [iQOS] aerosols by ~54-99.9% compared to [cigarette smoke]," and by "38.2%-99.8%" "[w]hen normalized to nicotine yield." *Id.* at 33. With respect to the Four Undisclosed Studies, the FDA made the following conclusion:

> There are potentially concerning chemicals in [iQOS] aerosols. The applicant conducted a non-targeted differential screening assay, which found the three [iQOS] aerosols contain higher levels of some chemicals than [cigarette] smoke—four of these are possible or probable carcinogens and possibly genotoxic. However, based on current knowledge, the toxic exposures from all three [iQOS] aerosols are reduced compared to [cigarette smoke], and many of the known HPHCs found in [cigarette] smoke are very low or undetectable in [iQOS] aerosols.

April 2019 Scientific Review at 91-92. In that day's press release, the FDA announced that authorization of iQOS for the U.S. market was "appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes." McDonough Decl., Ex. 3 at 3.

On July 7, 2020, the FDA authorized the marketing of iQOS as a MRTP.[2] *See* McDonough Decl., Ex. 2. Although PMI had sought both a "risk modification" and "exposure modification" order, "the FDA determined that the evidence did not support risk modification orders at [that] time but that it did support issuing exposure modification orders for these products." *Id.* at 2. Pursuant to that authorization, PMI was permitted to market iQOS with the following information:

> AVAILABLE EVIDENCE TO DATE:
>
> - The IQOS system heats tobacco but does not burn it.
> - This significantly reduces the production of harmful and potentially harmful chemicals.

[2] The Complaint, filed on September 28, 2020, contains no reference to the FDA's MRTP authorization. The Court may nonetheless take judicial notice of that document "because it is publicly available and its accuracy cannot reasonably be questioned." *See In re Actos End-Payor Antitrust Litig.*, 848 F.3d at 96 n.7.

- Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.

Id. at 2. The FDA's "toxological assessment also found that, compared with cigarette smoke, IQOS aerosols contain considerably lower levels of potential carcinogens and toxic chemicals that can harm the respiratory or reproductive systems." *Id.* at 3. Noting that "there were some chemicals that were higher in [iQOS] aerosol than in combusted cigarette smoke," the FDA explained in a letter to PMI that "[a]dditional research must be conducted to better characterize the potential impact of these exposures." Dkt. 142, Declaration of David A. Rosenfeld, Ex. A at 7.

The scientific review accompanying the FDA authorization reached the following conclusion:

> Although the available scientific evidence shows that the IQOS system produces lower concentrations of many harmful and potentially harmful constituents (HPHCs) compared to cigarette smoke and the non-clinical data suggests a favorable toxicological profile of the IQOS system compared to combusted cigarettes, the overall body of evidence was not sufficient to demonstrate that completely switching from combusted cigarettes to the IQOS system reduces the risk of tobacco-related disease or harm.

McDonough Decl., Ex. 13 ("June 2020 Scientific Review") at 9. In contrast to the risk-modification order, which "requires scientific evidence showing actual risk reduction," the FDA concluded "[w]ith respect [to] the exposure modification order request" that iQOS demonstrated that "a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies." *Id.* at 11. The review went on to say that "[a]lthough some chemicals of potential concern (not on FDA's HPHC list) may be higher in IQOS users, the increase in these constituents does not impact the conclusion that the substantial reductions in HPHCs and findings from the toxicological evidence are reasonably likely to translate to lower risk of tobacco-related morbidity and mortality." *Id.* at 73.

E. Defendants' Statements During the Class Period

During the Class Period, which extends from July 26, 2026 through April 18, 2018, *see* Compl. ¶ 1, Defendants made the following statements, which Plaintiffs maintain were false or misleading in light of the undisclosed results from the four NTDS studies.

In its form 10-Q for the second quarter of 2016, submitted to the SEC on July 26, 2016, PMI represented that the study results of its "six short-term clinical studies" showed "a substantial reduction in relevant biomarkers of exposure to harmful or potentially harmful constituents ('HPHCs') in adult consumers who switched to iQOS compared to adult consumers who continued to smoke cigarettes over a five-day period." *Id.* ¶ 326. The Company repeated those statements in its third quarter submission to the SEC on October 26, 2016, and its annual 10-K report on February 14, 2017. *Id.* ¶¶ 337, 339. In its annual report, the Company similarly noted that it had by then completed eight clinical studies, some of which "also measured six clinical risk markers…. associated with disease mechanisms known to be affected by smoking and to reverse upon cessation." *Id.* ¶ 339. According to PMI, the results indicated "that switching completely to IQOS led to an overall improvement of clinical risk markers affected by smoking after only three months." *Id.* Those statements were repeated in the Company's first quarter and second quarter submissions to the SEC, on April 27, 2017 and July 27, 2017 respectively. *Id.* ¶¶ 345, 357.

The Company also made a number of specific references to aerosol characterizations—the apparent subject of the Four Undisclosed Studies. In a September 29, 2016 call with investors, Peitsch stated that the Company was following a "multi-step research program that starts with aerosol characterization" and "progresses to clinical studies." *Id.* ¶ 328. According to Peitsch, the Company's methodology involved demonstrating "a key component of the risk reduction potential" "[a]t each step" "before proceeding to the next step." *Id.* At an October 8, 2016

presentation before the Japanese Medical Society of Alcohol and Addiction Studies, Defendant Patrick Picavet, the Company's Director of Medical Affairs, stated that the "aerosol" generated by iQOS had 90 to 95% less HPHCs compared to a reference cigarette and was "90 to 95% less toxic than smoke from a reference cigarette." *Id.* ¶ 335. During a May 2017 scientific update, the Company represented that "[i]n vitro and in vivo assessments of the aerosol reveal reduced toxicity and no new hazards." *Id.* ¶ 351. When asked during a June 21, 2017 interview why the public should believe PMI's studies after the Company "had lied to the public for decades," Defendant André Calantzopoulos—PMI's Chief Executive Officer, *see id.* ¶ 23—responded that the proof was in the data, and that the aerosol of iQOS "is analyzed quickly, in comparison with cigarette smoke you immediately recognize the decline of dangerous substances." *Id.* ¶ 353. Throughout the Class Period, the Company represented that HPHCs were reduced in iQOS aerosol by "96% compared to cigarettes," *id.* ¶ 331, or by "90-95%," *id.* ¶¶ 335, 347, 359.

PMI also made a number of statements touting the general health benefits and/or reduced harm of iQOS. During the above-referenced September 2016 investor call, Peitsch stated that "scientific research conducted across a range of studies demonstrates that IQOS has a wide array of benefits compared to smoking cigarettes," and that "the totality of the evidence generated to-date supports our conclusion that IQOS has the potential to reduce the risk of smoking-related diseases in adult smokers who switch to it completely." *Id.* ¶ 328. Picavet stated that "[t]he totality of evidence to date regarding the potential harm reduction effects of [iQOS] are very encouraging both in terms of individual risk reduction and at a population level." *Id.* ¶ 331. In a March 27, 2017 press release, the Company reported that "[s]tudies conducted to date clearly indicate that IQOS is likely to present less risk of harm compared to smoking." *Id.* ¶¶ 341, 343. PMI similarly reported, in a May 2017 scientific update, that the Company's "studies are very

advanced and point in the direction of risk reduction." *Id.* ¶ 349. The 2016 Sustainability Report also reported that "[f]indings to date show that switching completely to iQOS is likely to present less risk of harm than continued smoking." *Id.* ¶ 359. The Company reiterated those statements in its November and December 2017 scientific updates for smoke-free products. *Id.* ¶¶ 363, 365, 367.

Lastly, on December 20, 2017—*i.e.*, thirteen days after disclosure of the NTDS studies to the FDA—the Company represented in a briefing document that "the results of all of its nonclinical studies 'confirm[ed] that iQOS aerosol does not introduce any new or increased risks compared with tobacco smoke.'" *Id.* ¶ 317.

II. Procedural History

Plaintiff the City of Westland Police and Fire Retirement System, a purchaser of PMI common stock during the Class Period, commenced this action on September 5, 2018 by filing a class action complaint against Defendants PMI, Calantzopoulos, Martin King, and Jacek Olczak. Dkt. 9. On February 25, 2019, the Court appointed Union Asset Management Holding AG and Teamsters Local 710 Pension Fund as co-lead plaintiffs and consolidated three related actions. Dkts. 82, 83. Plaintiffs filed a Consolidated Amended Class Action Complaint ("First Amended Complaint") on May 10, 2019, which added Picavet, Peitsch, and Frank Lüdicke as named defendants, and identified roughly seventy statements as false and/or misleading. Dkt. 92.

On February 4, 2020, the Court granted Defendants' motion to dismiss the First Amended Complaint, dismissing all claims with prejudice with the exception of those that concerned the Four Undisclosed Studies. Feb. 2020 Opinion at 42. Finding it "possible that, if given the opportunity to re-plead, Plaintiffs could assert facts plausibly supporting their claims related to Defendants' failure to timely disclose the four studies," the Court instructed Plaintiffs to explain

"with specificity … how the results of the undisclosed studies undercut the truthfulness of Defendants' statements about reduced risk and/or reduced exposure." *Id.* at 29-30 (internal quotation marks omitted). Plaintiffs timely filed the Complaint on September 28, 2020. Dkt. 134. Defendants, arguing that Plaintiffs had failed to heed the Court's instruction, filed the instant motion to dismiss. Dkt. 137. Oral argument was held on August 24, 2021. *See* Dkt. 155.

STANDARD OF REVIEW

I. Motions to Dismiss Under Federal Rule of Civil Procedure 12(b)(6)

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To make that determination, the Court must "accept[] all factual allegations as true, but giv[e] no effect to legal conclusions couched as factual allegations." *Stadnick*, 861 F.3d at 35 (internal quotation marks omitted). The Court may also consider any "statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff[s] and upon which [they] relied" in bringing this action. *ATSI Commc'ns*, 493 F.3d at 98. The Court may also take judicial notice of documents that are "publicly available" and whose "accuracy cannot reasonably be questioned." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016) (citing Fed. R. Evid. 201(b)). That category includes FDA approvals, *see In re Actos End-Payor Antitrust Litig.*, 848 F.3d at 96, and encompasses the scientific reviews and press releases that accompanied those approvals. *See Koublani v. Cochlear Ltd.*, No. 2:20-cv-1741 (DRH) (AYS), 2021 WL

2577068, at *5 (E.D.N.Y. June 23, 2021) ("District courts may take judicial notice of public records of the FDA on a motion to dismiss.").

II. Motions to Dismiss Under Federal Rule of Civil Procedure 9(b) and the PLSRA

This action for securities fraud is also subject to the heightened pleading requirements of Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *See, e.g.*, *ECA, Local 134 IBEW Joint Pension Tr. of Chicago v. J.P. Morgan Chase Co*., 553 F.3d 187, 196 (2d Cir. 2009). The PSLRA requires plaintiffs alleging securities fraud to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief . . . all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). "Similarly, Rule 9(b) requires that a complaint ... specify the statements that the plaintiff contends were fraudulent and "explain why the statements were fraudulent." *Abramson v. Newlink Genetics Corp*., 965 F.3d 165, 173 (2d Cir. 2020) (internal quotation marks omitted).

The PLSRA further requires that securities-fraud complaints "'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 345 (2005) (quoting 15 U.S.C. §§ 78u–4(b)(2)). "Allegations that are conclusory or unsupported by factual assertions are insufficient." *ATSI Commc'ns*, 493 F.3d at 99.

DISCUSSION

The principal issue in this motion is whether Plaintiffs have plausibly alleged that the results of the four aerosol studies either contradicted or rendered misleading Defendants' positive statements about iQOS.

Defendants argue that dismissal is warranted because Plaintiffs have failed to set forth particularized allegations that the challenged statements were materially false or misleading at the time they were made, or that any Defendant acted with fraudulent intent. Defendants further assert that the FDA's authorization of iQOS as a MRTP—a decision that was made 30 months after the Four Undisclosed Studies were provided to the FDA—undercuts any allegation of falsity. Mot. at 2.

Plaintiffs maintain that they have specifically pled that the Four Undisclosed Studies contradict, or at the very least substantially undermine, Defendants' affirmative representations about iQOS. Opp. at 2. At oral argument, Plaintiffs clarified that their allegations of falsity focus on Defendants' representations that iQOS reduces the risk of harm to users, rather than on claims about exposure to harmful chemicals. *See* Dkt. 155, Oral Argument Transcript ("Tr.") 11-12. In their view, those statements not only lacked any support in the scientific evidence available to PMI at the time that they were made but cannot be vindicated by the FDA's authorization, because iQOS received only an "exposure modification" order. *See id.* at 12.

I. Whether Defendants Violated Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5

Under Section 10(b) of the Securities Exchange Act, it is

> unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange ... [t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement any manipulative or deceptive device or contrivance in contravention of

> such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78j(b).

Rule 10b-5, promulgated by the SEC under Section 10(b) to define 'manipulative and deceptive devices,' prohibits persons from "(1) making 'any untrue statement of a material fact' and (2) from 'omit[ting] to state a material fact necessary in order to make [ ] statements made, in the light of the circumstances under which they were made, not misleading' in connection with the purchase or sale of any security." *Abramson*, 965 F.3d at 174 (quoting 17 C.F.R. § 240.10b-5(b)). While "the first part of this language unambiguously renders untrue statements of fact actionable," "the second part of this language, which does not cabin 'statements' with the modifier 'of a material fact,' renders both statements of fact and those of opinion actionable when such statements would be misleading without the contextualization of material facts." *Id*.

To maintain a private damages action under Section 10(b) and Rule 10b-5, "a plaintiff must prove (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Stoneridge Inv. Partners, LLC v. Sci.-Atlanta*, 552 U.S. 148, 157 (2008). Defendants' motion challenges only the first two factors.

A. Whether Plaintiff Adequately Alleges that Defendants' Statements Were False or Misleading

Plaintiffs challenge 22 statements related to the iQOS studies, made over an 18-month period, from July 26, 2016 to December 20, 2017. *See* Compl. ¶¶ 326-370. These statements can be grouped into three broad categories: 1) statements about the potential of iQOS to reduce the risk of harm to users; 2) factual descriptions of the clinical studies that PMI did disclose prior to

December 7, 2017; and 3) statements regarding the chemical composition of iQOS aerosol. The Court analyzes each group of statements in turn.

1. Defendants' Statements About Reduced Risk

The first category of alleged misrepresentations—those in which PMI or the Individual Defendants expressed positive interpretations of the available data as it pertained to the risk of iQOS—includes statements to the effect that iQOS "has a wide array of benefits compared to smoking cigarettes," Compl. ¶ 328, that "it has the potential to reduce the risk of smoking-related diseases," *id.*, that the totality of the evidence regarding harm reduction effects is "very encouraging," *id.* ¶ 331, and that studies indicate that iQOS "is likely to present less risk of harm compared to smoking," *id.* ¶¶ 341, 343. *See also id.* ¶¶ 359, 363, 365, 367, 369 (stating that the findings indicate that switching to iQOS is likely to present less risk of harm than continued smoking).

Plaintiffs assert that such statements were materially false and misleading primarily because the Company failed to also disclose that it "had recently completed four scientific studies showing that iQOS contained significantly larger amounts of some harmful chemicals than conventional cigarettes." *Id.* ¶ 342; *see id.* ¶¶ 330, 332, 360, 364, 366, 368, 370. At oral argument, Plaintiffs asserted that these representations were literally false, in that they lacked any support in the scientific evidence and were contradicted by the four studies. *See* Tr. 23-24.

Considering the totality of the facts alleged, the Court is not persuaded that failure to disclose allegedly adverse results from some studies rendered Defendants' general statements either false or misleading. As an initial matter, "[c]ourts have repeatedly held" that statements like these—*i.e.*, "publicly stated interpretations of the results of various clinical studies"—are "opinions because reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543

(S.D.N.Y. 2015) (internal quotation marks and alterations omitted), *aff'd sub nom., Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016). Categorizing Defendants' statements as opinion makes sense here because the propositions that iQOS had "the potential" to reduce risk or was "likely" to present a reduced risk of harm compared to smoke are not objectively falsifiable. The more pertinent question is therefore whether failure to disclose allegedly adverse results rendered those statements misleading by omission. It is well-established that a statement of opinion "'is not misleading simply because the issuer knows, but fails to disclose, some fact cutting the other way.'" *Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016) (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 189 (2015)). Put another way, a statement of opinion is misleading by omission only to the extent that the "omitted contrary facts substantially undermine the conclusion a reasonable investor would reach from a statement." *Abramson*, 965 F.3d at 177.

The Complaint makes clear that Defendants had a reasonable basis for making the above-cited statements of opinion. That is all that is required under the securities laws. *See Tongue*, 816 F.3d at 212 (stating that defendants are "only tasked with making statements that 'fairly align[ed] with the information in the issuer's possession at the time.'" (quoting *Omnicare,* 575 U.S. at 189)). From 2013 to 2015, PMI conducted eight clinical studies with adult smokers that the Company interpreted as indicating a reduction in "clinical risk markers … associated with disease mechanisms." Compl. ¶¶ 50-53, 63, 339. Although Plaintiffs challenge the wisdom of these studies' methodologies, they do not dispute the veracity of their results as reported by PMI. Those studies provided Plaintiffs with a reasonable basis to characterize iQOS as either less harmful or more beneficial than cigarettes. Nowhere in the Complaint do Plaintiffs allege that Defendants' interpretation of its clinical data was irrational or unreasonable. As the Second Circuit has stated,

"where a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement." *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2013).

Nor do the results from the four studies "substantially undermine" Defendants' statements. *See Abramson*, 965 F.3d at 177. The FDA—after evaluating the totality of the scientific evidence produced by Defendants including the Four Undisclosed Studies—similarly concluded that "IQOS aerosols contain considerably lower levels of potential carcinogens and toxic chemicals that can harm the respiratory or reproductive systems," McDonough Decl., Ex. 3 at 3, and that "a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies," June 2020 Scientific Review at 11. In fact, the FDA specifically determined that the elevated chemicals revealed in the Four Undisclosed Studies did not undermine the above conclusions, stating that "the increase in these constituents does not impact the conclusion that the substantial reductions in HPHCs and findings from the toxicological evidence are reasonably likely to translate to lower risk of tobacco-related morbidity and mortality," *id.* at 73.

The denial of PMI's request for a risk-modification order, a fact that Plaintiffs insist proves the falsity of the statements concerning harm reduction, does not alter the Court's conclusion. The FDA did not deny the order because the available data indicated that risk reduction was unlikely, but rather because the data was insufficient to demonstrate actual risk reduction. *See* June 2020 Scientific Review at 11. That finding is not inconsistent with Defendants' statements about the iQOS's potential or the likelihood that it would be less harmful than cigarettes.

That the FDA essentially endorsed Defendants' statements about its scientific data, even after considering the studies that Plaintiffs characterize as contradictory, severely undercuts any allegation that the statements were false or misleading when made. Because the allegedly contrary

facts that Defendants omitted did not contradict, or substantially undermine, their statements about risk, those statements were not misleading by omission. *See Omnicare*, 575 U.S. at 190 ("A reasonable investor does not expect that *every* fact known to an issuer supports its opinion statement."). For similar reasons, the Court cannot credit Plaintiff's theory that Defendants' statements to the effect that IQOS had "potential to or was "likely" to present less risk of harm, *see, e.g.,* Compl. ¶¶ 328, 341, lacked scientific support. In these circumstances, the "absence of any serious conflict" between Defendants' statements interpreting their own data and the FDA's ultimate interpretation of that same data is "fatal to Plaintiffs' case." *Tongue*, 816 F.3d at 212.

2. Factual Statements About Defendants' Clinical Studies

Plaintiffs' allegations of falsity with respect to Defendants' factual statements about their clinical studies suffer from similar deficiencies. As an initial matter, Defendants rightly point out that the Complaint nowhere asserts PMI's disclosures about its clinical iQOS studies, *i.e.*, those that tested the effect of iQOS on humans, were not true as a literal matter. Instead, Plaintiffs argue that Defendants' repeated citation of the positive results of the Company's clinical trials were misleading because they "gave investors the impression that the Company had disclosed all material information in its possession related to the toxicity of iQOS … as compared to cigarettes." Compl. ¶ 338; *see also id.* ¶¶ 327, 338, 340, 346, 348, 358. Defendants correctly assert that "Plaintiffs do not identify a single statement in which Defendants represented to investors that PMI had disclosed all of its scientific data and study results." Mot. at 13. In other words, Plaintiffs' theory of falsity with respect to these statements is again a theory of omission. So long as the omission of information does not render disclosed statements misleading, however, there is no generalized duty to "disclose negative facts." *See Barilli v. Sky Solar Holdings, Ltd.,* 389 F. Supp. 3d 232, 252 (S.D.N.Y. 2019).

The Court finds that Plaintiffs have failed to plausibly allege that Defendants' factually accurate statements about their clinical trials were rendered misleading by virtue of the failure to disclose results from a different category of studies. "The law is well settled . . . that so-called 'half-truths'—literally true statements that create a materially misleading impression—will support claims for securities fraud." *S.E.C. v. Gabelli*, 653 F.3d 49, 57 (2d Cir. 2011), *rev'd on other grounds*, *Gabelli v. S.E.C.*, 568 U.S. 442 (2013). When a defendant makes a disclosure about a particular topic, "the representation must be complete and accurate." *Meyer v. Jinkosolar Holdings Co.,* 761 F.3d 245, 250–51 (2d Cir. 2014) (internal quotation marks omitted). Within this framework, a plaintiff may adequately plead falsity by 'half-truth' with specific allegations that the defendant possessed information at the time the challenged statement was made that both concerned the topic referenced in that statement and contradicted representations in that statement. *See In re Ferroglobe PLC Sec. Litig.*, No. 1:19-CV-00629 (RA), 2020 WL 6585715, at *6 (S.D.N.Y. Nov. 10, 2020) (citing cases).

In assessing whether a statement is misleading by omission, the Court must adopt the perspective of a "reasonable investor," and consider the "'customs and practices of the relevant industry.'" *Abramson,* 965 F.3d at 175 (quoting *Omnicare*, 575 U.S. at 190). Applying that framework, the Court finds that the Complaint contain no allegations from which it could reasonably infer that an investor in the cigarette-alternative market would have interpreted the reporting of clinical results as necessarily implying the release of all available, non-clinical, data on the subject. Plaintiffs do not allege that Defendants made any statement that even contained that implication. *Cf. Abramson*, 965 F.3d at 177-78 (statement that "all the major [American] studies" indicated a particular survival rate for pancreatic cancer could lead a reasonable person to think that "no meaningful evidence existed to rebut the proposition").

Nor do Plaintiffs plausibly allege that the Four Undisclosed Studies contradict any representation made by PMI about the results of the clinical studies. In part, this is so because the studies, as the Complaint makes clear, were distinct in kind. Whereas the challenged statements specifically referred to "biomarkers," "clinical risk markers" and "disease mechanisms," *i.e.*, the effects of iQOS on human biology, the undisclosed studies merely measured the presence of chemical compounds in the product's aerosol, without any reference to their effect on humans. Indeed, the Complaint repeatedly critiques the Four Undisclosed Studies for failing to measure the toxicological profile of the chemicals which those studies identified as existing in elevated quantities in iQOS aerosol. *See, e.g.,* Compl. ¶ 100 ("even though these 30 chemicals occurred in significantly higher amounts in iQOS than conventional cigarettes, the Company performed no research to analyze the level of harm to consumers upon inhalation."). PMI specifically disclosed to the TPSAC that it had not "evaluate[d] the effect that inhaling these chemicals had on human subjects." *Id.* ¶ 98. In short, the Four Undisclosed Studies measured exposure to chemicals, not the harm of those chemicals. Because the undisclosed studies did not purport to measure the type of data that the Company presented in its statements concerning the clinical studies, the omitted information was not plausibly contradictory.

Moreover, the FDA's subsequent approval of iQOS as an MRTP again undercuts any argument that the results of the Four Undisclosed Studies in any way contradicted PMI's reporting of its data. In this context, the FDA's endorsement of the Company's statements about the health risks of iQOS, as discussed above, is fatal to Plaintiffs' claims. *See Gillis v. QRX Pharma Ltd.,* 197 F. Supp. 3d 557, 597 (S.D.N.Y. 2016) (dismissing claims for failure to adequately plead falsity in part because "the information which the [complaint] faults defendants for omitting [did] not contradict [their earlier] statements"); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d at 532 (finding falsity-

by-omission inadequately pled because omission was not "inconsistent" with defendants' statements). Accordingly, Plaintiffs have failed to plausibly allege that the omitted data was inconsistent with Defendants' statements about the clinical risk markers of iQOS.

3. Statements About iQOS Aerosol Characterization

Whether Plaintiffs have adequately pled the falsity of the next category of statements, which concerned the chemical composition of iQOS, presents a closer question. Defendants made numerous statements throughout the Class Period that touted, in sum and substance, that the Company's assessments of iQOS aerosol indicated "reduced toxicity and no new hazards." Compl. ¶ 351. Relatedly, the Company reported a decrease between 90-96% of HPHCs in iQOS aerosol on multiple occasions. *Id.* ¶¶ 331, 335, 347, 349.[3] Defendants' statements also appear to reference non-clinical studies of aerosol characterization—the same type of study that Plaintiffs allege went undisclosed. In other words, unlike their statements about the health effects of clinical studies, these statements placed at issue the very information that Defendants allegedly withheld.

On the one hand, the statements in this category appear, at first blush, inconsistent with the results of the Four Undisclosed Studies, which revealed elevated levels of multiple chemicals that Plaintiffs allege were widely known to be harmful. Plaintiffs' interpretation of the data from these studies—that it contradicted PMI's earlier statements about the reduction of harmful chemicals in iQOS aerosol—was apparently shared by members of the TPSAC, many of whom expressed concern about "the health implications of the additional compounds identified in the studies." *See id.* ¶¶ 124-127. At least initially, the FDA reacted to the Four Undisclosed Studies in a similar fashion. The agency's briefing document to TPSAC reported higher quantities of "compounds of

[3] At oral argument, Plaintiffs intimated that these statements were literally false, or at the very least, lacked sufficient support in the available data. *See* Tr. 25. Any argument that this quantitative data is objectively false is flatly contradicted by the April 2019 Scientific Review, which described a reduction in HPHCs of 54-99.9% and 38.2%-99.8%, as compared to cigarettes. April 2019 Scientific Review at 33.

toxicological concern," and noted that the lack of data on those compounds prevented a "determin[ation of] the risks of harm and tobacco-related diseases presented by iQOS." *Id.* ¶¶ 116, 120.

On the other hand, Defendants further a different interpretation of their data. In PMI's briefing document to the TPSAC, which was presented along with the Four Undisclosed Studies, the Company asserted that "the results of all of its nonclinical studies confirm[ed] that iQOS aerosol does not introduce any new or increased risks compared with tobacco smoke." *Id.* ¶ 369. Plaintiffs of course dispute this interpretation, and their analysis of the data may well be scientifically reasonable. Determining whether statements are plausibly alleged to be false, however, does not require the Court to choose between two competing analyses of data. As long as Defendants' "interpretation of data is itself reasonable, there is no false statement." *Kleinman*, 706 F.3d at 154.

Again, the reasonableness of the views expressed in Defendants' statements is supported by the FDA's effective endorsement of those views—which, as noted above, was based on the very information that Plaintiffs allege was withheld from the market. According to its July 2020 press release, the FDA's "toxological assessment . . . found that, compared with cigarette smoke, IQOS aerosol contain considerably lower levels of potential carcinogens and toxic chemicals that can harm the respiratory or reproductive systems." McDonough Decl., Ex 2 at 3. That assessment reiterated the FDA's earlier conclusion, based on "the FDA's scientific evaluation of the company's applications, peer- reviewed published literature and other sources, . . . that the aerosol produced by the IQOS Tobacco Heating System contains fewer toxic chemicals than cigarette smoke," *id.*, Ex. 3 at 3.

Because the FDA, after months-long analysis of the data, reached a conclusion about the toxicity of iQOS aerosol that was substantially similar to the one peddled by the Company during the Class Period, the Court cannot conclude that the Company's statements were either false or misleading when made. Moreover, because Defendants were under no obligation to disclose all facts that "cut[] the other way," *Tongue*, 816 F.3d at 210 (internal quotation marks omitted), their failure to disclose the elevated presence of other chemicals in iQOS aerosol did not render their interpretations misleading within the meaning of the securities laws.

In sum, because it is apparent from the Complaint—read in conjunction with documents that are either referenced therein or of which the Court may properly take judicial notice—that Defendants' statements constituted reasonable interpretations of the available data and were not substantially undermined by omitted facts, Plaintiffs have failed to adequately plead falsity. Plaintiffs' claims are thus dismissed on that basis.

B. Whether Plaintiffs Adequately Pled Scienter

Defendants also argue that Plaintiffs fail to adequately plead the requisite strong inference of scienter. For the reasons that follow, the Court again agrees.

To state a claim under Section 10(b), Plaintiffs must adequately allege that each Defendant acted with scienter when making the allegedly false or misleading representations. Where the defendant is a corporation like PMI, Plaintiffs must allege "that an agent of the corporation committed a culpable act with the requisite scienter, and that the act (and accompanying mental state) are attributable to" the entity. *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 195 (2d Cir. 2008) (citation omitted). "[P]laintiffs must state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Novak v. Kasaks*, 216 F.3d 300, 315 (2d Cir. 2000) (internal quotation marks omitted).

A complaint will survive a motion to dismiss "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.,* 551 U.S. 308, 324 (2007).

In practice, "the scienter requirement is met where the complaint alleges facts showing either: 1) a motive and opportunity to commit the fraud; or 2) strong circumstantial evidence of conscious misbehavior or recklessness." *Emps. Ret. Sys. of Gov't of the Virgin Islands v. Blanford*, 794 F.3d 297, 306 (2d Cir. 2015) (internal quotation marks omitted). To adequately plead motive and opportunity, a plaintiff must allege that the defendant "benefitted in some concrete and personal way from the purported fraud." *Novak*, 216 F.3d at 307-08. On that subject, the Court previously held that Plaintiffs' allegations of Calantzopoulos's two stock sales did not support an inference of scienter because the public record indicated that his shareholdings in PMI actually increased during the Class Period. Feb. 2020 Opinion at 38-39 (citing *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009)). As the Complaint does not contain any supplementary allegations concerning Calantzopoulos's trading patterns, the Court again concludes that Plaintiffs have failed to adequately plead that any individual defendant had a motive to conceal material information from the investing public.

Absent a showing of motive, "the strength of the [plaintiff's] circumstantial allegations must be correspondingly greater." *ECA, Local 134 IBEW Joint Pension Tr.,* 553 F.3d at 199 (internal quotation marks omitted). An inference of conscious misbehavior or recklessness arises where the complaint sufficiently alleges that the defendants "knew facts or had access to information suggesting that their public statements were not accurate" or "failed to check information they had a duty to monitor." *Novak*, 216 F.3d at 311. The evidence must create the

inference that "defendants engaged in conscious misstatements with the intent to deceive." *Id.* at 312.

The circumstantial allegations of scienter contained in the Complaint do not meet this standard. This action is premised on the claim that PMI sat on the results of the Four Undisclosed Studies for months after the initial submission of the MRTPA, and disclosed them to the FDA at the last possible moment, presumably in order to prevent a fulsome review by the TPSAC. But this theory lacks sufficient factual support from the Complaint. The FDA's approval of the Company's MRTPA, 30 months after they submitted the Four Undisclosed Studies, suggests that the delay provided little benefit to Defendants. Moreover, Plaintiffs fail to plausibly allege that any of the Individual Defendants were aware of the results of any of the undisclosed studies when they made the challenged statements. *See* Feb. 2020 Opinion at 40-41 ("'boilerplate allegations that defendants knew or should have known of fraudulent conduct based solely on their executive positions are insufficient', standing alone, 'to plead scienter'" (quoting *In re Sotheby's Holdings, Inc.*, No. 00-CV-1041 (DLC), 2000 WL 1234601, at *7 (S.D.N.Y. Aug. 31, 2000))).

According to Plaintiffs, the results of NTDS studies would have been "evident" as soon as the studies ended, *i.e.*, by June 2016 and January 2017. Compl. ¶ 106. That assertion is supported by a "former employee who worked at [PMI] during the Class Period, was involved in the Company's iQOS trials, and was familiar with the time it takes for the results of such studies to be available internally at [PMI]." *Id.* Plaintiffs also proffer the opinion of a pharmaceutical expert with 22 years of consulting experience who, upon review of the studies and a description of their methodologies, confirmed the former employee's conclusion "that the results of the Four Undisclosed Studies were evident when the studies ended, or at most a few weeks thereafter, and that the reports describing the studies could have been issued in a matter of weeks after the studies'

completion." *Id.* ¶ 107. Even accepting these allegations as true, as the Court must in adjudicating a motion to dismiss, the Complaint still fails to plausibly allege that any individual defendant was aware of those studies' results at the time of their statements. This failure is fatal to the claims against the Individual Defendants and the Company. Absent a plausible allegation that an "agent" of PMI knowingly made a false or misleading statement, the Court cannot impute a "culpable act" to the Company. *See Teamsters Local 445 Freight Div. Pension Fund*, 531 F.3d at 195.

Allegations that the results would have been "evident" or "available" within the Company or that descriptive reports "could have been issued" in a matter of weeks say nothing about whether and to what extent that information was or would have been presented to top-level executives like the Individual Defendants alleged to have made false statements. Defendants rightly point out that the "Complaint contains no particularized allegations whatsoever about Defendants' subjective awareness of the four … studies …, let alone the timing of any such awareness." Mot. at 15-16. Although the unnamed former employee may have been familiar in broad strokes with the procedure concerning non-clinical studies, there is no allegation that he or she had any direct conduct with any individual defendant. Plaintiff's expert cannot, of course, provide any indication about the way in which scientific studies were communicated internally within PMI. Nor does Calantzopoulos's vague statement in June 2017 that "[t]he aerosol of [iQOS] is analyzed quickly," Compl. ¶ 365, establish anything about his knowledge of the results of these particular studies. At bottom, Plaintiffs ask the Court to infer that the Individual Defendants must have known about the studies given their high-level positions and the importance of this product to the Company. The Court declines to make such an inference.

Courts within the Second Circuit have found a failure to plead a strong inference of scienter where, as here, the plaintiffs failed to allege with particularity that defendants had access to

information that suggested the inaccuracy of their public statements. *See, e.g., Schwab v. E*Trade Fin. Corp*., 285 F. Supp. 3d 745, 757 (S.D.N.Y.), *aff'd*, 752 F. App'x 56 (2d Cir. 2018) ("[B]oilerplate allegations that defendants knew or should have known of fraudulent conduct based solely on their board membership or executive positions are insufficient to plead scienter."); *Local No. 38 Int'l Bhd. of Elec. Workers Pension Fund v. Am. Exp. Co*., 724 F. Supp. 2d 447, 462 (S.D.N.Y. 2010), *aff'd sub nom., Local No. 38 Int'l Bhd. of Elec. Workers Pension Fund v. Am. Express Co*., 430 F. App'x 63 (2d Cir. 2011) (holding that "assertions that certain information was the 'sort of measurement' or 'would have been' reviewed by the individual defendants are too speculative to give rise to a strong inference of scienter"); *cf*. *In re Avon Sec. Litig*., No. 19 CIV. 01420 (CM), 2019 WL 6115349, at *1 (S.D.N.Y. Nov. 18, 2019) (finding scienter adequately pled where multiple confidential witnesses specifically alleged that defendants received "daily updates" and "monthly forecasts" with facts that would suggest their public statements were inaccurate).

The Court accordingly concludes that Plaintiffs have not alleged sufficient facts to raise a strong inference of scienter as to any individual defendant or as to PMI. In the Court's view, the facts alleged in the Complaint make the opposing inference—that Defendants did not purposely withhold from the market a subset of studies, which they later disclosed to the FDA (as one of fourteen amendments to their original application), and which not only failed to contradict their positive statements but appeared to support FDA approval—more compelling. *See Tellabs,* 551 U.S. at 324. Plaintiffs' failure to adequately plead scienter provides an alternate basis for dismissal of their claims under Section 10(b).

II. Whether Defendants Violated Section 20(a) of the Securities Exchange Act

Plaintiff further alleges that the Individual Defendants should be held separately liable as "control persons" under Section 20(a) of the Exchange Act. Liability under Section 20(a) is derivative. "In order to establish a prima facie case of controlling-person liability, a plaintiff must show a primary violation by the controlled person and control of the primary violator by the targeted defendant, and show that the controlling person was in some meaningful sense a culpable participant in the fraud perpetrated by the controlled person." *S.E.C. v. First Jersey Sec., Inc.,* 101 F.3d 1450, 1472 (2d Cir. 1996) (internal quotation marks, brackets, and citations omitted); *accord Wilson v. Merrill Lynch & Co.*, 671 F.3d 120, 139 (2d Cir. 2011).

Because Plaintiffs have failed to make a prima facie case of a "primary violation" under Section 10(b), they have not sufficiently pled that Defendants violated Section 20(a). Accordingly, those claims are dismissed.

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss Plaintiffs' complaint is GRANTED with prejudice. The Clerk of Court is respectfully directed to terminate items 137 and 139 on the docket and to close this case.

SO ORDERED.

Dated: September 10, 2021
New York, New York

Ronnie Abrams
United States District Judge